Filing Date: March 31, 2004

Title:

COMPOUNDS AND METHODS FOR PHARMICO-GENE THERAPY OF EPITHELIAL SODIUM CHANNEL ASSOCIATED

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Dkt: 875.085ŪS1

DISORDERS

IN THE SPECIFICATION

Please amend the paragraph beginning on page 43, line 15 as follows:

These formulations can contain pharmaceutically acceptable vehicles and adjuvants which are well known in the prior art. It is possible, for example, to prepare solutions using one or more organic solvent(s) that is/are acceptable from the physiological standpoint, chosen, in addition to water, from solvents such as acetone, ethanol, isopropyl alcohol, glycol ethers such as the products sold under the name "Dowanol", polyglycols and polyethylene glycols, C₁-C₄ alkyl esters of short-chain acids, preferably ethyl or isopropyl lactate, fatty acid triglycerides such as the products marketed under the name MIGLYOL® "Miglyol", isopropyl myristate, animal, mineral and vegetable oils and polysiloxanes.

Please amend the table beginning on page 75 as follows:

Table 2. In Vivo Enhancement of FVIII rAAV Transduction

Day 14 Results		
Sample	Animal # and Final Result ([[DF*]]ng/mL) Coatest (mU/mL)
Group 1 Vehicle		
	801 < 0.63	0
	804 < 0.63	0
	805 < 0.63	0
	847 < 0.63	0
Group 2 AAV2/5-HFN3/EBP-FVIII		
	816 < 0.63	0
	817 < 0.63	0
	818 0.92	0
	819 < 0.63	0
	820 < .63	0
	834 0.9	0
Group 2 AAV2/5-HFN3/EBP-FVIII + Doxi	1	
	870 60.45	171
	871 26.29	0

AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.116 – EXPEDITED PROCEDURE

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DISORDERS

872 12.395	14
873 44.3	30
874 12.135	122
875 31.04	94

2.X.10, Day 25 FVIII ELISA

Sample	Animal # and Final Result	
Group 1 Vehicle		
	806 < 0.63	0
	807 < 0.63	0
	808 < 0.63	0
	849 < 0.63	0
Group 2 AAV2/5-HFN3/EBP-FV	/III	
	821 < 0.63	0
	822 < 0.63	0
	823 < 0.63	0
	824 1.27	0
	825 0.72	0
	833 0.74	0
Group 3 AAV2/5-HFN3/EBP-FV	VIII + Doxil (no spikes)	
-	841 16.785	49.833
	842 12.425	37.282
	843 13.685	41.466
	844 35.225	91.842
	845 7.815	12.974
	846 24.02	54.853